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| 09 759,877      | 01 12 2001  | Stephen W. Noble JR. | P04808US0 P111 1319 | 2539             |

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MCKEE, VOORHEES & SEASE, P.L.C.  
ATTN: PIONEER HI-BRED  
801 GRAND AVENUE, SUITE 3200  
DES MOINES, IA 50309-2721

EXAMINER

KRUSE, DAVID H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 07 16 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/759,877

Applicant(s)

NOBLE, STEPHEN W.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 12 January 2001 has been considered, a copy of which is attached hereto.

### ***Specification***

2. The disclosure is objected to because of the following informalities: On page 7, last paragraph, the ATCC Accession Number has been left blank at lines 4 and 5. In addition, at page 53, there is no indication of the ATCC Accession Number for the deposited 34M94 hybrid maize line.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 1, 5, 6, 7, 12 and 16, are objected to because of the following informalities:

At claims 1, 5 and 7 the ATCC Accession Number has been left blank.

At claim 6, the phrase "A tissue culture" should read -- The tissue culture -- in referring to claim 5.

At claims 12 and 16, the phrase "A hybrid maize plant" should read -- The hybrid maize plant -- in referring to claim 2.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-32 are indefinite because the designation "34M94" does not denote an art recognized designation of a corn plant and hence does not state the metes and bounds of the claimed invention. The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics of Applicant's corn hybrid line designated 34M94. Compliance with this requirement may be held in abeyance since Applicant's specification provides evidence that the deposit has been or will be made. Applicant must provide the appropriate amendment to insert the deposit information at the time of allowance in both the specification and the claims.

At claim 5, lines 3-4, the phrase "capable of expressing" is indefinite and does not state a positive feature of the regenerated plants, the phrase should read -- that expresses --.

At claim 6, lines 1-2, the phrase "the cells or protoplasts being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

At claim 7, lines 1-2, the phrase "and capable of expressing" is indefinite and does not state a positive feature of the regenerated plant, the phrase should read -- that expresses --.

Claim 8 is indefinite because the plant of claim 2 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

Claims 9, 13, 17, 22, 26 and 30 are indefinite because the claims do not set forth any positive method steps leading to the maize plant at line 1 of the claims. Hence, it is unclear what the metes and bounds of the claimed methods are.

Claims 10, 14, 18, 23, 27 and 31 are indefinite because they are drawn to a "maize plant breeding program" while the claims to which they depend are drawn to a method. Appropriate correction is required.

At claims 11, 15, 19, 24, 28 and 32, the phrases "excellent grain yield potential", "strong stalks" and "particularly suited...of the United States", for example, are relative and do not state the metes and bounds of the claimed invention.

Claims 16 and 29 are indefinite because a hybrid maize plant is not produced by a backcrossing technique. Hence, it is unclear what the metes and bounds of these claims are.

At claims 11, 15, 19, 24, 28 and 32, line 2, the phrase "capable of expressing" is indefinite because it does not state a positive feature of the claimed invention.

Claim 21 is indefinite because the plant of claim 20 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11, 12, 15, 16, 19, 24, 25, 28, 29 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants and transgenic corn plants having undisclosed identifying characteristics whereby only the characteristics of the deposited maize line 34M94 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 12 and 25, the effect of transgenes on the physiological and morphological characteristic of a transgenic 34M94 maize plant or progeny thereof, is not sufficiently described where by one of skill in the art could recognize the claimed maize plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different maize plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny

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plants are disclosed in the specification. While claims 11, 15, 19, 24, 28 and 32 set forth at least two 34M94 traits, because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish 34M94 progeny maize plants.

Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited maize line 34M94. Accordingly, there is a lack of adequate description of the claimed progeny maize plants. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

8. Claims 13, 14, 17, 18, 26, 27, 30 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because Applicant has failed to adequately describe the maize plants at claims 12, 16, 25 and 29 the methods for developing a maize plant in a maize plant breeding program of the instant claims are not enabled. One skilled in the art would not know how to use a plant that has not been adequately described in a method of developing a maize plant in a maize breeding program, regardless of the technique used.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 11, 15-19, 24, 28, 29-31 and 32 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hoffbeck (US Patent 6,211,445, filed 1 March 1999).

Hoffbeck discloses a hybrid maize plant designated 34W67 (see claim 2), which Applicant admits is similar to the hybrid maize plant of the instant invention (see page 22, paragraph 3 of the instant application). Said 34W67 hybrid maize plant inherently discloses such relative traits as "excellent grain yield potential", "particularly suited to the Central Corn Belt region of the United States" and "a relative maturity of approximately 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain" (see for example claim 9). Applicant should also note that



because the limitations set forth in the claims lack a comparative basis as set forth in the 112 second paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Hoffbeck in the instant reference. While the hybrid maize plant of Hoffbeck is designated 34W67 and the hybrid maize plant of the instant claims is designated 34M94, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art.

Hoffbeck does not specifically disclose a method of producing maize plants using native or transformed 34M94 as a parent in an unspecified number of crosses with unspecified second parents.

The maize plant or its parts of claims 11, 16, and 24 would have been *prima facie* obvious to one of skill in the art at the time of applicant's invention because, depending upon what second maize plant one of skill in the art had selected, the resulting maize seed and progeny could be genetically, morphologically and physiologically indistinguishable from that of the instant claims. In addition, method of developing a maize plant-breeding program of claims 17, 18, 30 and 31 would have been obvious in view of Hoffbeck (see claim 27 for example). Similarly, the maize plant or its parts of claims 15, 19, 28, 29 and 32 would have been obvious in view of the teachings of the Hoffbeck reference because depending upon what second maize plant one of skill selects in producing said maize plant, the resulting progeny could be genetically, physiologically and morphologically indistinguishable from that of the claimed maize plant, given the loss of 34M94-derived genetic material or a transgene with each cross to a non-34M94 or untransformed parent. See *In re Thorpe*, 227 USPQ 964, 966 (Fed.

Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

**Conclusion**

12. Claims 1-10, 12-14, 20-23 and 25-27 appear to be free of the prior art because it neither suggests nor teaches the 34M94 hybrid maize plant or a maize plant having all of the morphological and physiological characteristics of the 34M94 hybrid maize plant of the instant claims or methods of use.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

David H. Kruse, Ph.D.  
9 July 2002

